APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Richard L. Dunn et al.	Examiner: Elizabeth R. MacNeill
Serial No.: 10/634,656	Group Art Unit: 3767
Filed: August 05, 2003	Docket: 1195.323US1

For: COUPLING SYRINGE SYSTEM AND METHODS FOR OBTAINING A MIXED COMPOSITION

APPEAL BRIEF UNDER 37 CFR § 41.37

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on September 9, 2009, from the Final Rejection of claims 1 and 3-25 of the above-identified application, as set forth in the Final Office Action mailed on March 9, 2009.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of the pending claims.

1. REAL PARTY IN INTEREST

The real party in interest, as of the filing of the Notice of Appeal on September 9, 2009, of the above-captioned patent application was QLT USA, INC. However, on October 1, 2009, the real party in interest changed from QLT USA, INC. to TOLMAR THERAPEUTICS, INC. This change was in the name only and was not a change in the entity itself. Should any further information be needed to satisfy 37 CFR § 41.8, Appellants kindly request a telephonic communication with the Appellants' representative. As noted below, Appellants' representative can be reached by telephone at (612) 371-2106.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on August 5, 2003 with claims 1-14. A non-final Office Action was mailed October 4, 2004. Appellants filed a response to the non-final Office Action on December 30, 2004. A final Office Action was mailed May 6, 2005. Appellants filed a response to the final Office Action on August 3, 2005. Appellants filed a Notice of Appeal in response to the final Office Action on September 6, 2005. An Advisory Action was mailed September 12, 2005. Appellants filed a response to the Advisory Action on October 3, 2005. Appellants filed an Appeal Brief on November 7, 2005. An Examiner's Answer was mailed January 26, 2006. Appellants filed a Reply Brief on March 27, 2006. A Notification of Non-Compliant Appeal Brief was mailed July 28, 2006. Appellants filed a Substitute Appeal Brief on August 28, 2006. An Examiner's Answer was mailed February 8, 2007. Appellants filed a Reply Brief on April 9, 2007. A Decision on Appeal was mailed December 10, 2007. Appellants filed a Request for Continued Examination and a Request to Reopen Prosecution on February 11, 2008. A Notice of Abandonment was mistakenly mailed February 19, 2008. Appellants filed a Petition to Withdraw Holding of Abandonment on April 16, 2008. A Decision on the Petition to Withdraw Holding of Abandonment was mailed October 20, 2008. A non-final Office Action was mailed October 23, 2008. Appellants filed a response to the non-final Office Action on January 19, 2009. A final Office Action was mailed March 9, 2009. Appellants filed a Notice of Appeal on September 9, 2009. Claims 1 and 3-25 stand rejected, remain pending, and are the basis for this Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated March 9, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

INDEPENDENT CLAIM 1

1. A coupling syringe system comprising:

a first syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with an integral male end portion and a locking ring, wherein the locking ring is spaced from an outer surface of the male end portion (*FIGS. 1-6; page 6, lines 16-21, 27-28*);

a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with an inner surface of the first syringe barrel (*FIGS. 1, 2, 4, and 6; page 7, lines 22-24*);

a second syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip with an integral female end portion and one or more exteriorly protruding members adapted to detachably fit the locking ring, wherein the female end portion has an opening defined by an opening wall, which supports the one or more exteriorly protruding members (*FIGS. 1, 2, and 5; page 7, lines 7-10 and 16-17*); and

a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with an inner surface of the second syringe barrel (*FIGS. 1, 2, 3, and 6; page 8, lines 9-11*),

wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion, thereby allowing for a single, fluid tight attachment site configured for back and forth transfer of one or more compositions between the first syringe and second syringes (*Page 5, lines 11-13, 18-24, 30-33; page 12, lines 9-10; page 15, line 8*).

INDEPENDENT CLAIM 21

21. A coupling syringe system for forming a mixed medical composition, the system consisting of:

a first single dose syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including an outwardly projecting flange and a first syringe tip with an integral male end portion and a locking ring, wherein the locking ring is spaced from an outer surface of the male end portion, the first syringe barrel having a first syringe inner surface (*FIGS. 1-6; Page 6, lines 16-28*);

a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with the first syringe inner surface (*FIGS. 1, 2, 4, and 6; page 7, lines 22-24*);

a second single dose syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including an outwardly projecting flange and a second syringe tip with an integral female end portion, wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring and an opening defined by an opening wall, the second syringe barrel having a second syringe inner surface (*FIGS. 1, 2, and 5; page 7, lines 7-10 and 16-17*);

a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with the second syringe inner surface (*FIGS. 1, 2, 3, and 6; page 8, lines 9-11*);

a drug delivery system disposed in one of the first and second syringes; and

a drug disposed in the other of the first and second syringes (*Page 10, lines 8-18*),

wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion (*Page 5, lines 11-13, 18-24, 30-33; page 12, lines 9-10*).

Independent claims 1 and 21 are directed to a coupling syringe system identified generally by the numeral 1 in FIGS. 1-6. The syringe system includes a first syringe 13 and a second syringe 14. (FIGS. 1, 2, and 5). The first syringe 13 includes a first syringe barrel 2

having a first syringe open proximal end 4, a first syringe distal end 3, and a wall 5 extending between the ends to define a first fluid receiving chamber 6. Additionally, the distal end 3 of the first syringe barrel 2 is characterized with a tip 8. (FIG. 4). The tip 8 is provided with a male end portion 10 wherein the male end portion 10 is provided with a locking ring 11. (FIG. 4). A first syringe plunger 40 is disposed in the first fluid receiving chamber 6 and is in sliding fluid-tight engagement with the wall 5 of the first syringe barrel 2. (FIGS. 1, 2, 4, and 6). The second syringe 14 includes a second syringe barrel 18 having a second syringe open proximal end 20, a second syringe distal end 19, and a wall 21 extending between the ends to define a second fluid receiving chamber 22. (FIGS. 1, 2, and 5). Additionally, the distal end 19 of the second syringe barrel is characterized with a tip 25 provided with a female end portion 27 wherein the female end portion 27 is configured to detachably connect to the locking ring 11 via one or more exteriorly protruding members 30. (FIGS. 1 and 3). A second syringe plunger 90 is disposed in the second fluid receiving chamber 22 and is in sliding fluid-tight engagement with the wall 21 of the syringe barrel 18. (FIGS. 1, 2, 3, and 6). The female end portion 27 has an opening therein, which is sized and configured to receive the tip 8 of the male end portion 10 therein. (FIGS. 3 AND 4). The locking ring 11 couples the first syringe 13 to the second syringe 14 when the tip 8 of the male end portion 10 is disposed within the female end portion 27, thereby forming a fluid tight engagement. (Page 5, lines 18-24, 30-33).

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to each of the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Rejection under 35 U.S.C. 103(a) based on U.S. Patent No. 4,743,229 in view of U.S. Patent No. 5,616,133 (claims 1, 3-8, 10, 11 and 13-25)

Claims 1, 3-8, 10, 11, and 13-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133).

Rejection under 35 U.S.C. 103(a) based on U.S. Patent No. 4,743,229 in view of U.S. Patent No. 5,616,133, and further in view of U.S. Patent No. 4,629,455 (claims 9 and 12)

Claims 9 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu/Cardenas as applied above, and further in view of Kanno (U.S. Patent No. 4,629,455).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §103(a)

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.,* 411 F.3d 1332, 1336-37 (Fed.Cir. 2005). The legal conclusion that a claim is obvious within § 103(a) depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). The underlying factual issues set forth in *Graham* are as follows: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). To establish *prima facie* obviousness of a claimed combination, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); M.P.E.P. § 2143.03." All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970); M.P.E.P. § 2143.03. As part of establishing a *prima facie* case of obviousness, the Examiner's analysis must show that some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.* To facilitate review, this analysis should be made explicit. *KSR Int'l v. Teleflex Inc., et al.*, 127 S.Ct. 1727; 167 L.Ed 2d 705; 82 USPQ2d 1385 (2007) (citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

The Federal Circuit has stated:

> Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* (emphasis in original).

In re Fine, 837 F.2d 1071; 5 USPQ2d 1596 (Fed. Cir.1988).

The test for obviousness under §103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir.1985). The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed combination and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). The fact that a reference teaches away from a claimed combination is highly probative that the reference would not have rendered the claimed combination obvious to one of ordinary skill in the art. *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 15 USPQ2d 1704, 1713 (Tex. 1990). When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR Int'l v. Teleflex Inc., et al.*, 127 S.Ct. 1727; 167 L.Ed 2d 705; 82 USPQ2d 1385 (2007).

Further, conclusions of obviousness must be based on facts, not generality. *In re Warner*, 379 F.2d 1011, 1017 (C.C.P.A. 1967); *In re Freed*, 425 F.2d 785, 787 (C.C.P.A. 1970). In fact, there must be a rational underpinning grounded in evidence to support the legal conclusion of obviousness. The Federal Circuit has stated that, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006), citing *In re Lee*, 61 USPQ2d 1430 (Fed. Cir.2002); 72 FR 57527-28 (Oct. 10, 2007).

Moreover, "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006). This thought was recently echoed by the U.S. Supreme Court in *KSR Int'l v. Teleflex Inc., et al.*, 127 S.Ct. 1727; 167 L.Ed 2d 705; 82 USPQ2d 1385 (2007) (a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.).

B) Discussion of the rejection of claims 1, 5-8, 10-11, 13-14, 17-22 and 25 under 35 U.S.C. § 103(a) over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133).

Claims 1, 5-8, 10-11, 13-14, 17-22 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133).

Appellants assert that Chu and Cardenas, neither alone nor in combination, teach or suggest all of the elements of Appellants' claimed coupling syringe system. Thus, a *prima facie* case of obviousness has not and cannot be been made using such references. Additionally, Chu and Cardenas teach away from the claimed combination.

The instant claims recite a coupling syringe system comprising a first syringe including a first tip with an integral male end portion and a second syringe including a second tip with an integral female end portion. The integral male end portion of the first syringe and the integral female end portion of the second syringe are configured to directly couple to one another, thereby forming a single attachment site between the first and second syringes. Stated differently, Appellants' claimed syringe system forecloses the need for separate connection parts to attach the first and second syringes. A locking ring is spaced from an outer surface of the male end portion of the first syringe to allow for the single, fluid tight attachment between the first and second syringes. Further, Appellants' claim 1 recites back and forth transfer of one or more compositions between the first and second syringes, and claim 21 recites a drug delivery system disposed in one of the syringes and a drug disposed in the other syringe.

Chu describes a first syringe 12 and a second syringe 14 connected by a separate connector means 50. Chu states:

> The two syringes are connected by means of a relatively simple adapter system. First adapter 42 at substantially closed end 18 of the first syringe 12 is joined to second adapter 44 at substantially closed end 24 of the second syringe 14. .. .During admixture, the adapters are joined by connector means 50.

(Column 4, lines 45-52). FIG. 2 of Chu clearly shows that the connection means 50 is an element not integrated with (i.e., is a separate element from) both the first syringe 12 and the second syringe 14. Thus, Chu does not disclose the claimed integral male and female end portions that are configured to directly couple to one another, thereby forming a single

attachment site between first and second syringes. Additionally, Chu does not disclose a locking ring as recited in Appellants' claims.

Further, Chu neither discloses nor suggests back and forth transfer of compositions between the two syringes or a drug delivery system in one syringe and a drug disposed in the other. Instead, in Chu, collagen (a gelatin material) disposed in the second syringe is injected unidirectionally into particulate mineral material present in the first syringe to form a collagen-mineral paste. (Column 4, lines 22-31). Chu states that "[u]pon injection of collagen into the first syringe containing particulate mineral material, a substantially uniform collagen-mineral paste is quickly and easily formed within that syringe." (Column 3, lines 18-21; FIG. 3)(emphasis added). Thus, one composition is unidirectionally injected into the other composition with no back and forth motion in Chu.

Cardenas does not remedy the deficiencies of Chu. Cardenas discloses a syringe for use with an epidural catheter. The syringe has a check valve that allows anesthetic liquid to enter the syringe but prevents the liquid from leaving the syringe unless the syringe is connected to a special catheter connector which opens the check valve and allows the liquid to flow out of the syringe. This system prevents epidural anesthetic from being injected intravenously and likewise prevents intravenous medications from being injected into the epidural catheter (col. 2, lines 1-12; FIG. 4), since the syringe and connector must be used together to function properly.

In contrast to the claimed system, which has two coupled syringes and a locking ring, the system described in Cardenas has a single syringe, a catheter connector, and no locking ring. Additionally, unlike Appellants' claimed coupling syringe system, which mixes compositions back and forth, the single syringe of Cardenas provides unidirectional flow of a single anesthetic liquid into the catheter connector when the check valve is pushed open. No material is passed back and forth between two components of the system and no mixing of a drug delivery system and a drug occurs. Indeed, in Cardenas, the anesthetic material can only leave the syringe if the pusher component of the special catheter connector pushes the movable valve of the syringe away from the wall of the valve chamber to open a fluid path from the syringe into the connector (col. 4, lines 17-23; FIGS. 4 and 7).

The Examiner asserted that "the syringe disclosed by Cardenas is a mixing syringe in the same field of endeavor (medicament mixing devices) which includes an integral female luer..."

(page 2, lines 19-20 of the Office Action). Appellants disagree. As explained above, the system disclosed by Cardenas is for administration of liquid anesthetic, not mixing. The female luer lock portion of the syringe only attaches to a needle for uptake of liquid anesthesia (col. 3, lines 30-36; FIGS. 1 and 2) or to the special epidural catheter connector for unidirectional expulsion of the anesthesia. No mixing is disclosed.

Thus, Appellants assert that Chu and Cardenas, neither alone nor in combination, teach or suggest all of the elements of Appellants' claimed coupling syringe system. Accordingly, a *prima facie* case of obviousness has not been made.

Appellants additionally assert that Chu and Cardenas teach away from the claimed combination. First, the separate connector part of Chu teaches away from the integral connection configuration claimed by Appellants. More specifically, the Chu syringe system, when connected to the intermediately disposed separate connector part 50, structurally and functionally differs from the claimed syringe including the integral connection configuration. As one example, Appellants' invention provides a solution to the Appellants-recognized problem of mixing systems including two syringes with a separate connection part (i.e., a syringe system similar to Chu). Such problems include plug flow of contents in the separate connection part and additional leakage opportunities via more than one attachment site. For instance, Appellants state in their application:

> [An] independent coupling means…provides a space where there is very little agitation due to plug flow of the contents. The contents, therefore, do not mix well. Additionally, when the syringes are uncoupled (i.e., disengaged), the contents have to be aspirated out of the independent coupling means or they will be lost. In addition, the independent coupling means must be removed and discarded before attaching a needed to the delivery or injection syringe.

(Application at page 2, lines 3-9).

> The present invention provides a syringe system wherein components of a composition can be easily mixed by the end user without losing a significant amount of mixed composition during the mixing process and wherein the mixed composition can be easily and rapidly administered to a patient. The syringe system has a relatively few number of interconnecting parts, to minimize human error and to minimize sample loss. Additionally, the syringe system effectively mixes the contents located therein without sample loss, such that it can be approved by the FDA when used with drugs that must be administered in a known, discrete and precise amount (e.g., leuprolide acetate).

(Application at page 4, lines 11-20).

Second, in Chu, one composition is unidirectionally injected into the other composition, with no back and forth motion, to form a paste. Chu states that "[u]pon injection of collagen into

the first syringe containing particulate mineral material, a substantially uniform collagen-mineral paste is quickly and easily formed within that syringe." (column 3, lines 18-21; FIG. 3)(emphasis added). Thus, Chu teaches that a unidirectional motion, whereby a liquid composition is injected into a solid composition, sufficiently mixes the compositions to form the paste. The thick paste described in Chu would not (and need not) flow back and forth in the adapter between the syringes for mixing. Instead, Chu teaches that the unidirectional, single push transport of the collagen into the dry particulate mineral material is sufficient to mix together these two thick, viscous ingredients. This is a teaching away from the recited back and forth mixing of the compositions recited in the instant claims.

Cardenas also teaches away from the claimed combination. First, the Cardenas syringe includes a check valve that allows liquid to enter the syringe but prevents the liquid from leaving the syringe unless the syringe is connected to a special catheter connector, which opens the check valve and allows the liquid to flow out of the syringe. The pusher component of the catheter connector must be in contact with the valve to slide it away from the chamber wall for any flow to occur out of the syringe. When the valve is pushed away from the chamber wall by the pusher, the liquid flows between the outer edge 46 of the valve member 34 and the cylindrical wall 48 of the valve chamber 36, then between the legs 40 of the valve member 34 and into the hollow cylinder 12 of the syringe 10 (col. 3, lines 21-26). Without the pusher member in place, the valve moves back against the chamber wall and prevents flow out of the syringe. This valve/pusher combination teaches away from the open flow that accompanies back and forth mixing between two syringes, as recited in Appellants' claims. Second, the Cardenas syringe "can only inject into a special epidural catheter connector." (Col. 1, lines 61-63)(emphasis added). A person of skill in the art in possession of Cardenas would thus readily appreciate that the Cardenas syringe cannot be used for mixing compositions such as a drug and a drug delivery system back and forth. Instead, this syringe can only be used for administration of drugs into the epidural space of a patient. Thus, Cardenas also teaches away from the claimed combination.

In summary, Appellants assert that the cited documents, neither alone nor in combination, teach or suggest all of the elements of Appellants' claimed coupling syringe system. Thus, a *prima facie* case of obviousness has not been made. Additionally, Chu and Cardenas teach away from the claimed combination. Reversal of the Examiner's rejection under 35 U.S.C. § 103(a),

and a finding of allowance, of claims 1, 5-8, 10-11, 13-14, 17-22 and 25 is respectfully requested.

C) Discussion of the rejection of claims 3 and 4 under 35 U.S.C. § 103(a) over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133).

Regarding claims 3 and 4, the Examiner further asserted that Cardenas teaches a male luer (Figure 11) connected to a needle assembly (28), and concludes that the male luer of Chu is clearly capable of connection to the standard needle assembly shown in Cardenas.

First, while Chu recites a male luer at the end of the first syringe 12 and second syringe 14 (col. 4, lines 45-52), Chu does not disclose discharge through a needle or other discharge assembly. Instead, Chu discloses that the first syringe has an optional groove 60 which enables the barrel to be easily cut or broken after the addition of the collagen to the particulate material, so that the paste may then be extruded from the syringe for use (column 4, lines 60-66 and FIG. 3). Thus, Chu teaches away from the use of a needle for extrusion of the resultant paste.

Second, Appellants note that Figure 11 of Cardenas shows an unsuccessful attempt at injecting from a standard syringe with a needle into the described epidural catheter connector (*see also*, col. 2, lines 54-56). This figure demonstrates that the catheter connector will only function when coupled with the described syringe having a check valve. Thus, a person of skill in the art would readily appreciate, based on Figure 11, that attaching anything but the Cardenas syringe to the Cardenas catheter connector would result in a non-functional discharge assembly.

Thus, a person of skill in the art, in possession of Chu and Cardenas, would not be led to the discharge assembly or needle cannula and hub recited in the instant claims. Reversal of the Examiner's rejection under 35 U.S.C. § 103(a), and a finding of allowance, of claims 3 and 4 is requested.

D) Discussion of the rejection of claims 15, 16, 23 and 24 under 35 U.S.C. § 103(a) over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133).

Regarding claims 15, 16, 23 and 24, the Examiner further asserted that it would have been obvious "to use lyophilized leuprolide acetate with Poly (D,L-lactide-co-glycolide) (PLG) dissolved in a biocompatible solvent N-methyl 2-pyrrolidone as a simple substitution of one

known device for another since it is well known in the art that leuprolide acetate is used to treat endometriosis." First, Appellants submit that the Examiner's statement "substitution of one known device for another" is unclear and clarification is respectfully requested. Second, neither Chu nor Cardenas discloses leuprolide acetate, Poly (D,L-lactide-co-glycolide) or N-methyl 2-pyrrolidone, much less leuprolide acetate that is lyophilized or separating the Poly (D,L-lactide-co-glycolide), N-methyl 2-pyrrolidone and leuprolide acetate into separate syringes. Thus, the cited documents do not disclose all the elements of the claims. Third, it is not clear how the fact that leuprolide acetate is known to treat endometriosis would make obvious a coupling system that keeps the delivery system and the drug in two separate syringes, allowing for mixing immediately prior to administration. The Office must provide a specific reason to support an obvious rejection, e.g., a reason which is clear and particular and not a broad conclusory statement; however, no such reason has been provided. However, in the instant matter, the Office merely concludes that it would have been obvious to use the claimed components in the coupled syringe system.

Reversal of the Examiner's rejection under 35 U.S.C. § 103(a), and a finding of allowance, of claims 15, 16, 23 and 24 is respectfully requested.

E) Discussion of the rejection of claims 9 and 12 under 35 U.S.C. § 103(a) over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133) as applied to the claims above, and further in view of Kanno (U.S. Patent No. 4,629,455).

Claims 9 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu/Cardenas as applied to claims above, and further in view of Kanno (U.S. Patent No. 4,629,455). Appellants first reiterate that as discussed above, Chu and Cardenas do not teach or suggest every element of Appellants' claims. Further, Chu and Cardenas teach away from the claimed combination. Kanno does not remedy these deficiencies of Chu and Cardenas.

Kanno recites a rotatably coupled locking ring mounted on a medical instrument. Modifying the connecting structure of Chu with the connection member as taught by Kanno, as suggested by the Office Action, results in a connection element not integrated with either the first syringe 12 or the second syringe 14, (e.g., the connection element remains a separate element positioned between the first syringe 12 and the second syringe 14), in contrast to the instant

claims. Modifying the connecting structure of Cardenas with the connection member disclosed by Kanno results in a connection element having a check valve and a catheter connector with a pusher element, which opens the check valve and allows unidirectional flow of liquid out of the syringe. Thus, the references, even when combined, do not teach or suggest "a first syringe *including*...a first syringe tip with an *integral* male end portion and a locking ring...," "...a second syringe *including* a second syringe tip with an *integral* female end portion..." or "back and forth transfer of one or more compositions between the first syringe and second syringe," as recited in Appellants' claims.

The Examiner asserted that it would have been obvious to have modified the connecting structure of Chu/Cardenas with the connecting member taught by Kanno for the well known purpose of providing a male and female connection *alternative* that can be joined firmly with high reliability. Appellants submit that the term "alternative" infers that Chu and Cardenas, by themselves, recite suitable connection mechanisms in which a male and female element can be firmly joined. Indeed, Chu recites two connection schemes that join (in fluid communication) a first device to a second device and makes no mention of a need for additional connection alternatives (Chu, col. 4, lines 45-57). Cardenas recites a single connection scheme to join the first and second devices and states that the recited syringe "can only inject into a special epidural catheter connector" that pushes the syringe check valve with a pusher member to open fluid communication between the two devices (col. 1, lines 61-63; col. 3, lines 57-60). Accordingly, one of ordinary skill in the art in possession of Chu and Cardenas would have had no reason to consider additional connection alternatives to make a connection between two devices, such as a first syringe and a second syringe or discharge assembly.

Further yet, Appellants submit that Chu teaches away from being combined with, and/or modified in light of, Kanno. As one example, Chu recites that an object of the invention contained therein is structural simplicity and being inexpensive to construct (col. 2, lines 58-60). Kanno, on the other hand, recites a "rib in the threaded groove is placed into engagement with the threaded ridge by being deformed upon helical engagement with the threaded ridge." (Kanno, col. 3, lines 39-42). Kanno further recites that "because of the limited thickness [i.e., 0.15 to 1.50 mm], the rib 22 is fractured relatively easily by the threaded ridge 23 and the necessary frictional force is obtained between the fractured rib 22 and the threaded ridge 23." (col. 5, lines

24-27; col. 7, lines 28-33). That is, Kanno (in opposition to the objectives of Chu) recites a rib requiring precise (and thus manufacturably expensive) tolerancing.

Thus, Kanno does not cure the deficiencies of Chu and Cardenas. Reversal of the Examiner's rejection under 35 U.S.C. § 103(a), and a finding of allowance of all claims, is respectfully requested.

SUMMARY

For the reasons argued above, claims 1, 3-8, 10, 11, and 13-25 were not properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133). Further, claims 9 and 12 were not properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) in view of Cardenas (U.S. Patent No. 5,616,133) as applied above, and further in view of Kanno (U.S. Patent No. 4,629,455).

It is respectfully submitted that the art cited does not render the claims obvious and that the claims are patentable over the cited art. Reversal of the outstanding rejections and allowance of all pending claims is respectfully requested.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2106

Date January 7, 2010 By /Karen Himmel Ohlfest/
Karen Himmel Ohlfest
Reg. No. 58,663

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 7th day of January 2010.

DAWN M. POOLE

Name

/ Dawn M. Poole /

Signature

8. CLAIMS APPENDIX

1. A coupling syringe system comprising:

a first syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with an integral male end portion and a locking ring, wherein the locking ring is spaced from an outer surface of the male end portion;

a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with an inner surface of the first syringe barrel;

a second syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip with an integral female end portion and one or more exteriorly protruding members adapted to detachably fit the locking ring, wherein the female end portion has an opening defined by an opening wall, which supports the one or more exteriorly protruding members; and

a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with an inner surface of the second syringe barrel,

wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion, thereby allowing for a single, fluid tight attachment site configured for back and forth transfer of one or more compositions between the first syringe and second syringes.

2. (Cancelled)

3. The coupling syringe system of claim 1, wherein the locking ring is configured to detachably connect to a discharge assembly.

4. The coupling syringe system of claim 3, wherein the discharge assembly comprises a needle cannula and a hub joined to a proximal end of the cannula, and wherein the male end portion at least partially fits into, and frictionally engages, the hub when the discharge assembly and the locking ring are detachably connected.

5. The coupling syringe system of claim 1, wherein the integral female end portion of the second syringe is detachably connected to the integral male end portion of the first syringe via engagement of the one or more exteriorly protruding members and one or more threads on an inward-oriented surface of the locking ring, which extend toward a syringe axis.

6. The coupling syringe system of claim 1, wherein the integral female end portion of the second syringe is detached from the integral male end portion of the first syringe.

7. The coupling syringe system as recited in claim 1, further comprising an outwardly projecting flange near the first syringe proximal end.

8. The coupling syringe system as recited in claim 1, further comprising an outwardly projecting flange near the second syringe proximal end.

9. The coupling syringe system as recited in claim 1, wherein the locking ring is rotatably coupled relative to the integral male end portion of the first syringe.

10. The coupling syringe system as recited in claim 1, wherein the locking ring surrounds the male end portion and is threadingly coupled with the one or more exteriorly protruding members, and wherein the one or more exteriorly protruding members are disposed on an outward-oriented surface of the opening wall, extending away from a syringe axis, of the female end portion.

11. The coupling syringe system as recited in claim 1, wherein the integral male end portion of the first syringe is disposed within the integral female end portion of the second syringe.

12. The coupling syringe system as recited in claim 1, wherein the locking ring is rotatably coupled relative to the integral male end portion of the first syringe and the locking ring is threadingly coupled with the one or more exteriorly protruding members of the second syringe.

13. The coupling syringe system as recited in claim 1, wherein at least one of the first and second syringes contains therein a composition including a drug delivery system.

14. The coupling syringe system as recited in claim 13, wherein the other syringe contains therein a composition including a drug.

15. The coupling syringe system as recited in claim 14, wherein the drug includes lyophilized leuprolide acetate.

16. The coupling syringe system as recited in claim 13, wherein the drug delivery system includes Poly (D,L-lactide-co-glycolide) dissolved in a biocompatible solvent N-methyl 2-pyrrolidone.

17. The coupling syringe system as recited in claim 1, wherein the first syringe is directly coupled to the second syringe such that no independent coupling means is present therebetween.

18. The coupling syringe system as recited in claim 1, wherein the first syringe and the second syringe include single dose administration syringes.

19. The coupling syringe system as recited in claim 18, wherein a first dose administration syringe is approximately the same size as a second dose administration syringe.

20. The coupling syringe system as recited in claim 1, wherein the first syringe including the first syringe tip with the integral male end portion is defined by a unitary body; and

wherein the second syringe including the second syringe tip with the integral female end portion is defined by a unitary body.

21. A coupling syringe system for forming a mixed medical composition, the system consisting of:

a first single dose syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including an outwardly projecting flange and a first syringe tip with an integral male end portion and a locking ring, wherein the locking ring is spaced from an outer surface of the male end portion, the first syringe barrel having a first syringe inner surface;

a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with the first syringe inner surface;

a second single dose syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including an outwardly projecting flange and a second syringe tip with an integral female end portion, wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring and an opening defined by an opening wall, the second syringe barrel having a second syringe inner surface;

a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with the second syringe inner surface;

a drug delivery system disposed in one of the first and second syringes; and

a drug disposed in the other of the first and second syringes,

wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion.

22. The coupling syringe system as recited in claim 21, wherein the locking ring couples the first syringe to the second syringe and forms a fluid tight engagement configured for back and forth transfer of the drug delivery system and the drug between the syringes.

23. The coupling syringe system as recited in claim 21, wherein the drug includes lyophilized leuprolide acetate.

24. The coupling syringe system as recited in claim 21, wherein the drug delivery system includes Poly (D,L-lactide-co-glycolide) dissolved in a biocompatible solvent N-methyl 2-pyrrolidone.

25. The coupling syringe system as recited in claim 21, wherein, when the first and second syringes are coupled, movement of the first syringe plunger toward the second syringe effectuates delivery of one or both of the drug delivery system or the drug through the male end portion and directly into the second syringe barrel.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.